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K100386

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Submission: February 2, 2010

Sponsor: Changzhou Waston Medical Appliance Co,.Ltd
No.9, Wujin Rd, Wujin Hi-Tech Industry Zone
Changzhou, Jiangsu, 213164, China

Correspondent: Ms. Diana Hong / Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, No.19, Lane 999,Zhongshan Road (S-2),Shanghai, 200030, China

Proposed Device Disposable Circular Stapler WH-Y-25 / WH-Y-29 / WH-Y-32

Classification: Class II, GDW, 878.4750

Predicate Device: Chex™ Single Use Curved Intraluminal Circular Stapler as cleared in K090821.

Intended Use: The Disposable Circular Stapler is intended to be used throughout the alimentary tract for the creation of end-to-end and end-to-side anastomosis.

Device Description: The Disposable Circular Stapler places a circular, double staggered row of titanium staples and resects the excess tissue, creating a circular anastomosis. The instrument is activated by squeezing the handle firmly as far as it will go. It is applicable to end-to-end and end-to-side anastomosis. The proposed device is provided EO sterilized.

Testing Conclusion: Performance testing was conducted to validate and verify that the proposed device, Disposable Circular Stapler met all design specifications and was substantially equivalent to the predicate device.

SE Conclusion: The proposed device, Disposable Circular Stapler is claimed to be substantially equivalent to the predicate device, ChexTM Single Use Curved Intraluminal Circular Stapler as cleared in K090821.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 1 2010

Changzhou Watson Medical Applicance Co., Ltd.
% Shanghai Mid-Link Business Consulting Co., Ltd.
Ms. Diana Hong
Suite 5D, No. 19, Lane 999
Zhongshan Road (S-2)
Shanghai, 200003, China

Re: K100386
Trade/Device Name: Disposable Circular Stapler WH-Y-25/WH-Y-29/WH-Y-32
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 11, 2010
Received: February 16, 2010

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bruemp for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100386

Device Name: Disposable Circular Stapler

Indications for Use:

The Disposable Circular Stapler is intended to be used throughout the alimentary tract for the creation of end-to-end
and end-to-side anastomosis.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100386